

REMARKS

The Examiner claims to have received papers filed under 35 U.S.C § 119 (b) based on an application filed in Chili. However, there is no prior filed Chilean Application to which the instant Application can claim priority. These papers were not filed by either the Applicants or the Applicants' Attorney. It would appear that these papers relate to another US Patent Application.

Applicants do not wish to claim priority to this unrelated Chilean application, and therefore a new oath or declaration is not required, and hence is not being filed herewith.

Rejection of claims 1-5, 7, 8, 10, 20-24, 33 and 34 under 35 U.S.C. § 103 (a)

The Examiner has rejected claims 1-5, 7, 8, 10, 20-24, 33 and 34 under 35 U.S.C. § 103 (a) as being upatentable over Wagner *et al.*, Mandeville III *et al.*, Klofta *et al.* and Drake *et al.* all of which she asserts disclose the use of ionene polymers for the treatment of a microbial or a helminth infection.

The claimed invention is directed to a method of treating oral mucositis with ionene polymers. Oral mucositis is a specific disease affecting the oral cavity, resulting in inflammation and ulcers of the oral mucus membranes. Oral mucositis is typically a side-effect of anti-cancer treatments. In Claim 7, the oral mucositis is caused by anti-cancer therapy.

Drake *et al.* provides biological data to show that the disclosed polymers are effective in treating helminth infections *in vivo*. However, a helminth infection is not a microbial infection. Although the other prior art references cited by the Examiner teach treating microbial infections, very little biological data is presented to support these teachings. In fact, the only data presented in the cited art that illustrates anti-microbial activity of these compounds is an *in vitro* study presented in Mandeville *et al.* Treatment of oral mucositis is not taught or suggested in any of these references.

The Applicants' invention is non-obvious over the cited prior art because, *inter alia*, the effectiveness of ionene polymers in treating oral mucositis shown in the subject application is unexpected. Specifically, Applicants have unexpectedly found that an ionene polymer is greater than 50 times more effective than a common therapy for treating oral mucositis as disclosed by, for example, Ferretti *et al.* (cited in an IDS on 12/19/02 a copy of which is attached as Exhibit A). Ferretti *et al.* teach that chlorhexidine offers a therapeutic benefit in the resolution of oral mucositis. However, chlorhexidine was unsuccessful in treating oral mucositis in the hamster model disclosed in the subject application (page 3 lines 6 – 12), even at a concentration of 0.5% (v/v) (approximately 50 mg/mL). In contrast, the ionene polymer poly(4,4'-trimethylenebis-(1-methylpiperidinium)-alt-octane) was effective in reducing the severity of oral mucositis at concentrations as low as 1.0 mg/mL (see Example 19 pages 26-28). Therefore, the present invention represents a surprising and unexpected improvement in therapies for oral mucositis.

In addition to the above comments applying to the claim set as a whole, Applicants wish to offer separate comments pertaining to Claims 7, 8, 27 and 28 which contain the further limitation that oral mucositis is a side effect of anti-cancer therapies. None of the cited references disclose or otherwise suggest that ionene polymers can be used to treat oral mucositis that is a side effect of anti-cancer therapy. Moreover, none of the cited references provide the expectation that ionene polymers would have the effectiveness as shown, for example, in the animal model for oral-mucositis illustrated in Example 19. Accordingly, one of ordinary skill in the art would have no motivation to modify the teachings of Wagner *et al.*, Mandeville III *et al.*, Klofta *et al.* and Drake *et al.*, to obtain the invention of claims 7, 8, 27 or 28, let alone a reasonable expectation that such a modification would be successful.

In summation, none of the references cited teach or suggest that ionene polymers would be useful in treating oral mucositis, and none of the references demonstrate the use of ionene polymers in conjunction with the oral mucous membranes. Therefore the claims are unobvious and patentable in light of Wagner *et al.*, Mandeville III *et al.*, Klofta *et al.* or Drake *et al.*

Withdrawn Claims

Claims 9, 11-19 and 30-32, are withdrawn from consideration by the Examiner as being drawn to a non-elected species. Claims 9, 11-19 and 30-32, as amended, are dependent on Claim 2, and therefore should be examined upon allowance of Claim 2, which serves as a bridging claim. Rejoinder of Claims 9, 11-19 and 30-32 is respectfully requested upon allowance of Claim 2.

Information Disclosure Statement

A Supplemental Information Disclosure Statement (IDS) and PTO Form 1449 were filed on July 27, 2005. Entry of the IDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated:

December 1 2005